REMARKS

With this amendment claims 1-17 and 19-22 have been canceled. New claim 23 is added and claim 18 is amended.

Support for the amendment to claim 18 is found in the present specification at page 9, paragraph 3. The concentration of 9,19-cyclolanostan-3-ol or 24-methylene-9,19-cyclolanostan-3-ol of "0.001 to 10% by dry mass" as now recited in claim 18 as amended is the percentage in terms of mass when the drug is dried.

In other words, the drug defined by amended claim 18 contains 0.001 to 10% by mass of 9,19-cyclolanostan-3-ol or 24-methylene-9,19-cyclolanostan-3-ol with respect to a total dissolved solid in the drug.

Support for added claim 23 is found is found in the present specification from the last paragraph on page 22 to the first line on page 23.

Priority under 35 U.S.C. § 119

The Office Action summary indicates that the certified copies of the priority documents have not been received. Applicants submit herewith a copy of PCT/IB/304 (Attachment A) confirming that the foreign priority document JP 2004-283549 was transmitted by the International Bureau of WIPO.

Rejection under 35 U.S.C. § 102(b) (Yongchaiyudha)

Claim 18 is rejected under 35 U.S.C. § 102 (b) as being anticipated by Yongchaiyudha, et al. (Phytomedicine vol. 3(3) :241-243, 1996) as evidenced by Tanaka, et al. (Biol Pharm. Bull. 29 (7): 1418-1422 (2006)).

As established by the Declaration of Miyuki Tanaka submitted with the response filed May 15, 2008, Yongchaiyudha, et al. do not teach "a drug comprising 0.001 to 10% by dry mass of 9,19-cyclolanostan-3-ol or 24-methylene-9,19-cyclolanostan-3-ol" (claim 18) or "administering 9,19-cyclolanostan-3-ol or 24-methylene-9,19-cyclolanostan-3-ol to a subject whose hyperglycemia is to be improved in the amount of 0.001 to 50 mg/kg/day" (claim 23). Accordingly, the present claims are not anticipated by Yongchaiyudha, et al.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 102(b) (Abou Zeid)

Claim 18 is rejected under 35 U.S.C. § 102 (b) as being anticipated by Abou Zeid (Egypt. J. Phar. Sci. 39 (4-6): 379-398, 1998).

Abou Zeid does not teach "a drug comprising 0.001 to 10% by dry mass of 9,19-cyclolanostan-3-ol or 24-methylene-9,19-cyclolanostan-3-ol" (claim 18) or "administering 9,19-cyclolanostan-3-ol or 24-methylene-9,19-cyclolanostan-3-ol to a subject whose hyperglycemia is to be improved in the amount of 0.001 to 50 mg/kg/day" (claim 23). Accordingly, the present claims are not anticipated by Abou Zeid.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 5, 7, 12, 14, and 19 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Yongchaiyudha, et al. (Phytomedicine vol. 3(3) :241-243, 1996).

The Examiner points out that it would have been obvious to a skilled artisan to increase the concentration of Yongchaiyudha's composition, and that it is considered well within the skill of the skilled artisan to vary the concentration of Yongchaiyudha's composition, especially in view of the guidance given with regards to effective amounts in humans and rats.

However, if Yongchaiyudha's composition were concentrated by removal of water the concentration of 9,19-cyclolanostan-3-ol or 24-methylene-9,19-cyclolanostan-3-ol in the resulting composition would never exceed 0.001% by mass for the following reasons.

Applicants submit herewith a second Declaration by Miyuki Tanaka. The Declaration describes freeze-drying of 100 g of Aloe vera juice to remove water. The resultant dried sample had a mass of 1.9 g. Therefore, the Aloe vera juice contains about 1.9% by mass of solid content.

As described in the first Declaration of Miyuki Tanaka, submitted on April 10, 2008, 1 g of Aloe vera gel juice contains 9,19-cyclolanostan-3-ol or 24-methylene-9,19-cyclolanostan-3-ol in the amount of 222.8 ng and 162.3 ng, respectively.

Based upon this data, the concentration of the 9,19-cyclolanostan-3-ol in the Aloe vera gel juice of Yongchaiyudha, et al. is about 0.00011% by mass, and the concentration of 24-methylene-9,19-cyclolanostan-3-ol in the Aloe vera juice gel is about 0.000085% by mass with respect to total dissolved solid.

Therefore, the concentration of 9,19-cyclolanostan-3-ol and 24-methylene-9,19-cyclolanostan-3-ol in the Aloe vera gel juice of Yongchaiyudha, et al., even if concentrated, is clearly lower than 0.001% by mass as claimed.

When using a drug containing 9,19-cyclolanostan-3-ol or 24-methylene-9,19-cyclolanostan-3-ol at a high concentration according to the claimed invention, a sufficient improvement of hyperglycemia can be achieved with a small dose. If trying to achieve improvement of hyperglycemia using the Aloe vera gel juice of Yongchaiyudha, et al., a large dose would be needed. Administration of a large does greatly increases likelihood of unwanted side effects, such as hypoglycemia (present specification, page 7, paragraph 2) and purgation and weight reduction (Yongchaiyudha, et al. page 7, col. 1, paragraph 1 and page 8, col. 2). Although Yongchaiyudha, et al. report only 1 patient drop out for reason 2 (page 243, col. 1, last paragraph), there is no indication of the extent of termination due to reasons 1, 3 or 4 on page 8. By the practice of the claimed method, an effective amount of active ingredient is administered while minimizing side effects seen with administration of Aloe vera gel and juice.

Regarding claim 23, the range of "0.001 to 50 mg/kg/day" as set forth in claim 23 is neither taught not suggested by any of the cited references. Therefore, a skilled artisan could never administer 0.001 to 50 mg/kg/day to a person in need of treatment for hyperglycemia without consideration of the findings of the present invention.

In view of Applicants' amendments and arguments in light of the first and second 132 Declarations of Miyuki Tanaka, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather,

any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Nov. 7, 2008

By: _____

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ATTACHMENT A

PATENT COOPERATION TREATY

PCT/JP05/006021

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

KAWAGUCHI, Yoshiyuki
Acropolis 21 Building
6th floor
4-10, Higashi Nihonbashi 3-chome
Chuo-ku
Tokyo, 1030004
JAPON

Date of mailing *(day/month/year)* 30 May 2005 (30.05.2005)	
Applicant's or agent's file reference FP159-C4321	IMPORTANT NOTIFICATION
International application No. PCT/JP05/006021	International filing date *(day/month/year)* 30 March 2005 (30.03.2005)
International publication date *(day/month/year)*	Priority date *(day/month/year)* 29 September 2004 (29.09.2004)
Applicant MORINAGA MILK INDUSTRY CO., LTD. et al	

1. By means of this Form, which replaces any previously issued notification concerning submission or transmittal of priority documents, the applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to a date of receipt, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. *(If applicable)* The letters "NR" appearing in the right-hand column denote a priority document which, on the date of mailing of this Form, had not yet been received by the International Bureau under Rule 17.1(a) or (b). Where, under Rule 17.1(a), the priority document must be submitted by the applicant to the receiving Office or the International Bureau, but the applicant fails to submit the priority document within the applicable time limit under that Rule, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

3. *(If applicable)* An asterisk (*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b) (the priority document was received after the time limit prescribed in Rule 17.1(a) or the request to prepare and transmit the priority document was submitted to the receiving Office after the applicable time limit under Rule 17.1(b)). Even though the priority document was not furnished in compliance with Rule 17.1(a) or (b), the International Bureau will nevertheless transmit a copy of the document to the designated Offices, for their consideration. In case such a copy is not accepted by the designated Office as the priority document, Rule 17.1(c) provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
29 September 2004 (29.09.2004)	2004-283549	JP	12 May 2005 (12.05.2005)

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